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510(k) Summary

VAPR 3 Electrosurgical System and VAPR LD SUCTION and LP SUCTION Electrodes

K041135

Submitter's Name and Address:	DePuy Mitek a Johnson & Johnson company 249 Vanderbilt Avenue Norwood, MA 02062
Contact Person	Ruth C. Forstadt Project Management Lead, Regulatory Affairs DePuy Mitek a Johnson & Johnson company 249 Vanderbilt Avenue Norwood, MA 02062 Telephone: 781-251-3188 Facsimile: 781-278-9578 e-mail: rcforstad@ethus.jnj.com
Name of Medical Device	Classification Name: Electrosurgical cutting and coagulating device and accessories Common/Usual Name: Electrosurgical System and Electrodes Proprietary Name: VAPR 3 Electrosurgical System, VAPR LD SUCTION and LP SUCTION Electrodes
Substantial Equivalence	***VAPR 3 Electrosurgical System*** is substantially equivalent to theVAPR II Electrosurgical System (K002402, 8/31/2000). The ***VAPR LD Suction Electrode*** is substantially equivalent to the VAPR 2.3 Side Effect Electrode (K992876, 9/24/1999) and the VAPR 3.5 Suction Electrode (K002422, 8/31/2000) The ***VAPR LP Suction Electrode*** is substantially equivalent to the VAPR LD Suction Electrode, a modification to the VAPR 2.3 Side Effect Electrode (K992876, 9/24/1999) and the VAPR 3.5 Suction Electrode (K002422, 8/31/2000).
Device Classification	Electrosurgical cutting and coagulating device and accessories have been classified as Class II, GEI (21 CFR 878.4400).
Device Description	**VAPR 3 Electrosurgical System** is designed to provide soft tissue ablation (vaporization), contouring, cutting and hemostasis of blood

vessels during arthroscopic surgical procedures. The components of the system include a generator, handpiece and cable, electrodes, and footswitch.

The **VAPR LD and LP Suction Electrodes** are soft tissue ablation and dessication devices intended for use with the VAPR System. They extend the utility of the system by removing bubbles created during activation from the operating site.

Indications for Use

The **VAPR 3 Electrosurgical System**, when used with a VAPR Electrode, is intended for resection, ablation, excision of soft tissue, hemostasis of blood vessels and coagulation of soft tissues in patients requiring arthroscopic surgery of the knee, shoulder, andle, elbow and wrist.

The **VAPR LD SUCTION and LP SUCTION Electrodes,** when used with the VAPR Electrosurgical System, are intended for resection, ablation, excision of soft tissue, hemostasis of blood vessels and coagulation of soft tissues in patients requiring arthroscopic surgery of the knee, shoulder, andle, elbow and wrist.

Safety and Performance

In support of the 510(k), Mitek has provided certification of compliance to 21 CFR 820.30 Design Control requirements, descriptions of Mitek's subcontractor Design Control and Risk Analysis procedures, and the results of validation testing (performance testing) for the device modification.

Based on the Indications for Use, technological characteristics and safety and performance testing, the **VAPR 3 Electrosurgical System and VAPR LD and LP Suction Electrodes** have been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 0 2004

Mrs. Ruth C. Forstadt
Project Management Lead, Regulatory Affairs
DePuy Mitek
249 Vanderbilt Avenue
Norwood, Massachusetts 02062

Re: K041135
Trade/Device Name: VAPR 3 Electrosurgical System
Regulation Number: 21 CFR 878.4400, 21 CFR 888.1100
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Arthroscope
Regulatory Class: II
Product Code: GEI, HRX
Dated: April 29, 2004
Received: April 30, 2004

Dear Ms Forstadt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041135

Device Name: **VAPR 3 Electrosurgical System**
VAPR LD and LP Suction Electrodes

Indications For Use:

The **VAPR 3** Electrosurgical System, when used with a VAPR Electrode, is intended for resection, ablation, excision of soft tissue, hemostasis of blood vessels and coagulation of soft tissues in patients requiring arthroscopic surgery of the knee, shoulder, andle, elbow and wrist.

The **VAPR LD and LP Suction Electrodes,** when used with the VAPR Electrosurgical System, are intended for resection, ablation, excision of soft tissue, hemostasis of blood vessels and coagulation of soft tissues in patients requiring arthroscopic surgery of the knee, shoulder, andle, elbow and wrist.

Prescription Use ___x___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041135

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